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ENZO BIOCHEM, INC., Plaintiff-Appellant, v. GEN-PROBE INCORPORATED, and CHUGAI PHARMA U.S.A., INC. and CHUGAI PHARMACEUTICAL CO., LTD., and BIOMERIEUX, INC., and BECTON DICKINSON AND COMPANY, Defendants-Appellees, and BIOMERIEUX SA, Defendant.

01-1230

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

323 F.3d 956; 2002 U.S. App. LEXIS 28124

July 15, 2002, Decided

PRIOR HISTORY: [**1] Appealed from: United States District Court for the Southern District of New York. Judge Alvin K. Hellerstein. *Enzo Biochem, Inc. v. Gen-Probe Inc., 2001 U.S. Dist. LEXIS 23791 (S.D.N.Y., Apr. 4, 2001)*
Enzo Biochem, Inc. v. Gen-Probe Inc., 285 F.3d 1013, 2002 U.S. App. LEXIS 5642 (Fed. Cir., 2002)

DISPOSITION: REVERSED and REMANDED.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff patent assignee filed a patent infringement claim against defendant pharmaceutical companies. The United States District Court for the Southern District of New York had granted the pharmaceuticals' motion for summary judgment as the claims were invalid for failure to meet the written description requirement of *35 U.S.C.S. § 112*, para. 1. The judgment was upheld on appeal and the assignee petitioned for rehearing.

OVERVIEW: The patent was directed to nucleic acid probes that selectively hybridize to the genetic material of the bacteria that cause gonorrhea. The assignee deposited three nucleotide sequences in the form of a recombinant DNA molecule within a bacterial host in a public depository and noted their function in the specification. The circuit court vacated its previous decision and held that reference in a patent specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constituted an adequate description of the deposited material sufficient to comply with the written description requirement of *35 U.S.C.S. § 112*, para. 1. Some of the patent claims were not limited to the deposited sequences. The circuit court remanded those claims for the district court to determine whether one skilled in the art would consider the subject matter of the claims to be adequately described, recognizing the significance of the deposits and the scope of the claims.

OUTCOME: The circuit court concluded that the district court erred in granting summary judgment that the patent claims were invalid for failure to meet the written description requirement. The judgment was reversed and remanded for further consideration.

LexisNexis(R) Headnotes

Civil Procedure > Summary Judgment > Summary Judgment Standard
[HN1] Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. *Fed. R. Civ. P. 56(c)*. On motion for summary judgment, the court views the evidence and any disputed factual issues in the light most favorable to the party opposing the motion.

Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption
[HN2] A patent is presumed to be valid, *35 U.S.C.S. § 282*, and this presumption can be overcome only by facts supported by clear and convincing evidence to the contrary.

Patent Law > Claims & Specifications > Description Requirement > Proof
Patent Law > Claims & Specifications > Description Requirement > Elements
[HN3] Compliance with the written description requirement for patents is a question of fact.

Patent Law > Claims & Specifications > Definiteness > General Overview
Patent Law > Claims & Specifications > Description Requirement > General Overview
[HN4] See *35 U.S.C.S. § 112*, para. 1.

Patent Law > Claims & Specifications > Description Requirement > Written Description Versus Enablement
[HN5] The United States Court of Appeals for the Federal Circuit has interpreted *35 U.S.C.S. § 112* as requiring a written description of an invention separate from enablement. Compliance with the written description requirement is essentially a fact-based inquiry that will necessarily vary depending on the nature of the invention claimed. The court has also previously considered the written description requirement as applied to certain biotechnology patents, in which a gene material has been defined only by a statement of function or result, and has held that such a statement alone did not adequately describe the claimed invention.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Claims & Specifications > Definiteness > General Overview
Patent Law > Claims & Specifications > Description Requirement > General Overview
[HN6] An adequate written description of genetic material requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.

Patent Law > Claims & Specifications > Description Requirement > General Overview
[HN7] The United States Patent and Trademark Office has issued Guidelines governing its internal practice for addressing the written description requirement for genetic material. The Guidelines, like the Manual of Patent Examining Procedure, are not binding on courts, but may be given judicial notice to the extent they do not conflict with the statute.

Patent Law > Claims & Specifications > Description Requirement > Elements
Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
[HN8] In its Guidelines for Examination of Patent Applications Under the *35 U.S.C.S. § 112*, para. 1 "Written Description" Requirement, *66 Fed. Reg. 1099, 1106* (January 5, 2001), the United States Patent and Trademark Office has determined that the written description requirement can be met by showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

Patent Law > Claims & Specifications > Description Requirement > General Overview
[HN9] Reference in a patent specification to a deposit in a public depository of a nucleotide sequence, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of *35 U.S.C.S. § 112*, para. 1.

Patent Law > Claims & Specifications > Description Requirement > General Overview
[HN10] A description of what a material does, rather than of what it is, usually does not suffice for a patent specification. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview
Patent Law > Inequitable Conduct > General Overview
Patent Law > Claims & Specifications > Description Requirement > General Overview
[HN11] The purpose of the written description requirement of *35 U.S.C.S. § 112*, para. 1 is broader than to merely explain how to make and use; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. This statement, however, merely states a purpose of the written description requirement, viz., to ensure that the applicant had possession of the invention as of the desired filing date. It does not state that possession alone is always sufficient to meet that requirement.

Patent Law > Claims & Specifications > Description Requirement > General Overview
Patent Law > Date of Invention & Priority > General Overview
[HN12] As with "possession," proof of a reduction to practice may show priority of invention or allow one to

antedate a reference, but it does not by itself provide a written description in the patent specification.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
Patent Law > Date of Invention & Priority > Reduction to Practice
[HN13] Actual reduction to practice may be crucial in the relatively rare instances where the level of knowledge and level of skill are such that those of skill in the art cannot describe a composition structurally, or specify a process of making a composition by naming components and combining steps, in such a way as to distinguish the composition with particularity from all others. Guidelines for Examination of Patent Applications Under the *35 U.S.C. 112,* P 1 "Written Description" Requirement, *66 Fed. Reg. 1099, 1101* (January 5, 2001). For biological inventions, for which providing a description in written form is not practicable, one may nevertheless comply with the written description requirement by publicly depositing the biological material. That compliance is grounded on the fact of the deposit and the accession number in the specification, not because a reduction to practice has occurred. Such description is the quid pro quo of the patent system; the public must receive meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.

COUNSEL: Richard L. Delucia, Kenyon & Kenyon, of New York, New York, filed a petition for rehearing en banc for plaintiff-appellant. With him on the petition were Charles A. Weiss and Bradley S. Corsello.

The appellees filed a consolidated response to the petition for rehearing en banc. William F. Lee, Hale and Dorr LLP, of Boston, Massachusetts, for defendant-appellee Gen-Probe Incorporated. With him on the response was William G. McElwain.

Robert J. Gunther, Jr., Latham & Watkins, of New York, New York, for defendants-appellees Chugai Pharma U.S.A., Inc. and Chugai Pharmaceutical Co., Ltd. With him on the response was Jeffrey A. Tochner. Of counsel was Kurt M. Rogers.

Daniel A. Boehnen, McDonnell Boehnen Hulbert & Berghoff, of Chicago, Illinois, for defendant-appellee Biomerieux, Inc. With him on the response was Joshua R. Rich.

Donald R. Ware, Foley Hoag & Eliot LLP, of Boston, Massachusetts, for defendant-appellee Becton Dickinson and Company. With him on the response was Barbara A. Fiacco.

Frank P. Porcelli, Fish & Richardson [**2] P.C., of Boston, Massachusetts, filed a brief for amicus curiae Fish & Richardson P.C. Of counsel on the brief were Robert E. Hillman and Charles H. Sanders.

Mark S. Davies, Attorney, Appellate Staff, Civil Division, Department of Justice, of Washington, DC, filed an amicus curiae brief for the United States in support of rehearing en banc. With him on the brief were Robert D. McCallum, Jr., Assistant Attorney General, and Scott R. McIntosh, Attorney. Of counsel on the brief was John M. Whealan, Solicitor, U.S. Patent and Trademark Office, of Arlington, Virginia.

JUDGES: Before LOURIE, DYK, and PROST, Circuit Judges. LOURIE, Circuit Judge, with whom NEWMAN, Circuit Judge, joins, filed an opinion concurring in the court's decision not to hear the case en banc. NEWMAN, Circuit Judge, filed an opinion concurring in that decision. DYK, Circuit Judge, filed an opinion concurring in that decision. RADER, Circuit Judge, with whom GAJARSA and LINN, Circuit Judges, join, filed an opinion dissenting from that decision. LINN, Circuit Judge, with whom RADER and GAJARSA, Circuit Judges, join, filed an opinion dissenting from that decision.

OPINIONBY: LOURIE

OPINION:

[*960] ON PETITION FOR REHEARING

LOURIE, [**3] Circuit Judge.

Enzo Biochem, Inc. petitions for rehearing of this appeal following our prior decision, reported at *285 F.3d 1013, 62 USPQ2d 1289 (Fed. Cir. 2002)*, in which we affirmed the decision of the United States District Court for the Southern District of New York. The district court had granted Gen-Probe Incorporated, Chugai Pharma U.S.A., Inc., Chugai Pharmaceutical Co., Ltd., Biomerieux, Inc., Biomerieux SA, and Becton Dickinson and Company's (collectively, "the defendants'") motion for summary judgment that claims 1-6 of U.S. Patent *4,900,659* are invalid for failure to meet the written description requirement of *35 U.S.C. § 112,* P 1. *Enzo Biochem, Inc. v. Gen-Probe Inc., 2001 U.S. Dist. LEXIS 23791,* No. 99 Civ. 4548 (S.D.N.Y. Apr. 4, 2001) (final order). Having considered Enzo's petition for rehearing and the defendants' response, n1 we have determined that our prior decision that a deposit may not satisfy the written description requirement was incorrect. We

therefore grant Enzo's petition for rehearing, vacate the prior decision, and reverse the district court's grant of summary judgment that Enzo's claims are invalid for failure to meet the written description [**4] requirement. Because genuine issues of material fact exist regarding satisfaction of the written description requirement, we remand.

n1 Amicus curiae briefs were filed by the United States Patent and Trademark Office and Fish & Richardson P.C.

BACKGROUND

Enzo is the assignee of the *'659* patent, which is directed to nucleic acid probes that selectively hybridize to the genetic material of the bacteria that cause gonorrhea, Neisseria gonorrhoeae. N. gonorrhoeae reportedly has between eighty and ninety-three percent homology with Neisseria meningitidis. *'659* patent, col. 2, ll. 61-64. Such a high degree of homology has made detection of N. gonorrhoeae difficult, as any probe capable of detecting N. gonorrhoeae may also show a positive result when only N. meningitidis is present. Enzo recognized the need for a chromosomal DNA probe specific for N. [*961] gonorrhoeae, and it derived three such sequences that preferentially hybridized to six common strains of N. gonorrhoeae over six common [**5] strains of N. meningitidis. Id. at col. 3, l. 49 to col. 4, l. 14; col. 4, ll. 45-50. The inventors believed that if the preferential hybridization ratio of N. gonorrhoeae to N. meningitidis were greater than about five to one, then the "discrete nucleotide sequence [would] hybridize to virtually all strains of Neisseria gonorrhoeae and to no strain of Neisseria meningitidis." Id. at col. 12, ll. 60-65. The three sequences that the inventors actually derived had a selective hybridization ratio of greater than fifty. Id. at col. 13, ll. 9-15. Enzo deposited those sequences in the form of a recombinant DNA molecule within an E. coli bacterial host at the American Type Culture Collection. Id. at col. 13, ll. 27-31.

Claim 1 is as follows:

> 1. A composition of matter that is specific for Neisseria gonorrhoeae comprising at least one nucleotide sequence for which the ratio of the amount of said sequence which hybridizes to chromosomal DNA of Neisseria gonorrhoeae to the amount of said sequence which hybridizes to chromosomal DNA of Neisseria meningitidis is greater than about five, said ratio being obtained by a method comprising [**6] the following steps;
>
> (a) providing a radioactively labeled form of said nucleotide sequence;
>
> (b) providing a serial dilution series of purified chromosomal DNA from each of the N. gonorrhoeae strains; (1) ATCC 53420, (2) ATCC 53421, (3) ATCC 53422, (4) ATCC 53423, (5) ATCC 53424, (6) ATCC 53425, and forming test dots from each of said dilution series on a matrix;
>
> (c) providing a serial dilution series of purified nucleotide sequences from each of the N. meningitidis strains: (1) ATCC 53414, (2) ATCC 53415, (3) ATCC 53416, (4) ATCC 53417, (5) ATCC 53418, (6) ATCC 53419, and forming test dots from each of said dilution series on a matrix;
>
> (d) hybridizing equal portions of the labeled nucleotide sequences to the matrix provided in step (b) and (c), respectively; wherein the hybridization is conducted in a solution having a salt concentration of 2X SSC at (i) 65 degrees C. in cases in which the sequence has greater than 50 base pairs or (ii) at Tm (degrees C.) minus 30 degrees C. in cases in which the sequence has less than 50 base pairs, wherein Tm is the denaturation temperature of the sequence;
>
> (e) quantifying the labeled nucleotide sequence hybridized [**7] in step (d) to each test dot;
>
> (f) subtracting from the data of step (e) an averaged amount of radioactivity attributable to background to obtain a corrected amount of hybridized radioactivity at each test dot;
>
> (g) normalizing the data of step (f) by multiplying the amount of corrected radioactivity at each test dot by a factor which adjusts the amount of radioactivity to equal amounts of chromosomal DNA at each test dot;
>
> (h) selecting two normalized values that are most nearly the same and that correspond to adjacent members of the

> dilution series for each of the above strains of N. gonorrhoeae and obtaining the average of the selected values;
>
> (i) selecting two normalized values that are most nearly the same and that correspond to adjacent members of the dilution series for each of the above strains of N. meningitidis and [*962] obtaining the average of the selected values;
>
> (j) dividing the lowest average obtained in step (h) by the highest average obtained in step (i) to obtain said ratio.

Id. at col. 27, l. 29 to col. 28, l. 27 (emphasis added). Claims 2 and 3 depend from claim 1 and further limit the hybridization ratio to greater than about [**8] twenty-five and fifty, respectively. Id. at col. 2, ll. 27-30. Claim 4 is directed to the three deposited sequences (referenced by their accession numbers) and variants thereof as follows:

> 4. The composition of claim 1 wherein said nucleotide sequences are selected from the group consisting of:
>
> a. the Neisseria gonorroheae [sic] DNA insert of ATCC 53409, ATCC 53410 and ATCC 53411, and discrete nucleotide subsequences thereof,
>
> b. mutated discrete nucleotide sequences of any of the foregoing inserts that are within said hybridization ratio and subsequences thereof; and c. mixtures thereof.

Id. at col. 28, ll. 31-39. Claim 5 is directed to an assay for detection of N. gonorrhoeae using the composition of claim 1. Id. at ll. 40-46. Claim 6 further limits the method of claim 5 to the nucleotide sequences that Enzo deposited (i.e., those in claim 4) and variants thereof. Id. at ll. 47-56.

Enzo sued the defendants for infringement of the *'659* patent, and the defendants moved for summary judgment that the claims were invalid for failure to meet the written description requirement of *35 U.S.C. § 112*, P 1. The district [**9] court, in oral remarks from the bench, granted that motion. Tr. of Hr'g at 42, *Enzo Biochem, Inc. v. Gen-Probe, Inc., 2001 U.S. Dist. LEXIS 23792*, No. 99-CV-4548 (S.D.N.Y. Jan. 24, 2001). It concluded that the claimed composition of matter was defined only by its biological activity or function, viz., the ability to hybridize to N. gonorrhoeae in a ratio of better than about five with respect to N. meningitidis, which it was held was insufficient to satisfy the *§ 112*, P 1 requirement set forth in this court's holdings in *Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997)*, *Fiers v. Revel, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993)*, and *Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)*. Tr. of Hr'g at 28. The court rejected Enzo's argument that the reference in the specification to the deposits of biological materials in a public depository inherently disclosed that the inventors were in possession of the claimed sequences. Id. at 35. It distinguished this court's precedents concerning deposits as relating to the enablement requirement of *§ 112*, [**10] P 1. Id. at 38-40. Enzo appealed to this court; we have jurisdiction pursuant to *28 U.S.C. § 1295 (a)(1)*.

DISCUSSION

[HN1] Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. *Fed. R. Civ. P. 56(c)*; *Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986)*. On motion for summary judgment, the court views the evidence and any disputed factual issues in the light most favorable to the party opposing the motion. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (1986)*. [HN2] A patent is presumed to be valid, *35 U.S.C. § 282 (1994)*, and this presumption can be overcome only by facts supported by clear and convincing evidence to the contrary, see, e.g., *WMS Gaming, Inc. v. Int'l Game Tech., 184 F.3d 1339, 1355, 51 USPQ2d 1385, 1396-97 (Fed. Cir. 1999)*. [HN3] Compliance with the written description [*963] requirement is a question of fact. *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991)*. [**11]

Enzo argues that the testimony of its expert, Dr. Wetmer, raised a genuine factual issue whether the reference to the deposits inherently described the claimed nucleotide sequences. Enzo also argues that its description of the binding affinity of the claimed nucleotide sequences satisfies the requirement set forth in the Guidelines for Examination of Patent Applications Under the *35 U.S.C. 112*, P 1 "Written Description" Requirement, *66 Fed. Reg. 1099* (Jan. 5, 2001) ("Guidelines"). Enzo asserts that the court erred in not evaluating the patentability of the claims separately, pointing out that claims 4 and 6 are directed to the three deposited sequences and variations and mixtures thereof. Enzo further asserts that the claims per se meet the written description requirement because they appear in ipsis verbis in the written description. Enzo also argues

that this court's articulation of the written description requirement for genetic material in Eli Lilly should not apply to this case because Enzo reduced the invention to practice and deposited the derived biological materials, thereby demonstrating its "possession" of the invention. [**12]

The defendants respond that the district court properly granted summary judgment because the patent described the claimed nucleotide sequences only by their function, which they state is insufficient to meet the requirements of *§ 112*, P 1 as a matter of law, even as to the narrower claims directed to the deposited materials. The defendants also assert that Dr. Wetmur's opinion that the deposited genetic materials could have been sequenced did not cure the actual failure of the inventors to identify them by some distinguishing characteristic, such as their structure. Moreover, the defendants point out that claims 4 and 6, which are directed to the deposited materials, each cover a broad genus of nucleic acids. The defendants also urge that in ipsis verbis support for the claims in the specification does not per se establish compliance with the written description requirement. Finally, the defendants assert that the district court did not err in its determination that Enzo's "possession" of three nucleotide sequences that it reduced to practice and deposited nevertheless did not satisfy the written description requirement of *§ 112*, P 1.

The written description requirement [**13] of *§ 112*, P 1 is set forth as follows:

> [HN4] The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, P 1 (1994) (emphasis added). [HN5] We have interpreted that section as requiring a "written description" of an invention separate from enablement. *Vas-Cath, 935 F.2d at 1563, 19 USPQ2d at 1117* (recognizing the severability of the "written description" and "enablement" provisions of *§ 112*, P 1). Compliance with the written description requirement is essentially a fact-based inquiry that will "necessarily vary depending on the nature of the invention claimed." *Id.* (citing *In re Di Leone, 58 C.C.P.A. 925, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971))*. We have also previously considered the written description requirement as applied to certain biotechnology patents, [**14] in which a gene material has been defined only by a statement of function or result, and have held that [*964] such a statement alone did not adequately describe the claimed invention. *Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406*. In Eli Lilly, we concluded that a claim to a microorganism containing a human insulin cDNA was not adequately described by a statement that the invention included human insulin cDNA. *Id. at 1567, 43 USPQ2d at 1405*. The recitation of the term human insulin cDNA conveyed no distinguishing information about the identity of the claimed DNA sequence, such as its relevant structural or physical characteristics. *Id.* We stated that [HN6] an adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention," and that none of those descriptions appeared in that patent. *Id. at 1566, 43 USPQ2d at 1404* (quoting *Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606*). The specification in the Eli Lilly case thus did not show that the inventors had possession of [**15] human insulin cDNA.

It is not correct, however, that all functional descriptions of genetic material fail to meet the written description requirement. [HN7] The PTO has issued Guidelines governing its internal practice for addressing that issue. The Guidelines, like the Manual of Patent Examining Procedure ("MPEP"), are not binding on this court, but may be given judicial notice to the extent they do not conflict with the statute. See *Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 n.10, 33 USPQ2d 1823, 1828 n.10 (Fed. Cir. 1995)*. [HN8] In its Guidelines, the PTO has determined that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Guidelines, *66 Fed. Reg. at 1106* (emphasis added). For example, the PTO would find compliance with *§ 112*, P 1, for a claim to an "isolated antibody capable of binding to [**16] antigen X," notwithstanding the functional definition of the antibody, in light of "the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature." Synopsis of Application of Written Description Guidelines, at 60, available at http://www.uspto.gov/web/patents/guides.htm ("Application of Guidelines"). Thus, under the

Guidelines, the written description requirement would be met for all of the claims of the *'659* patent if the functional characteristic of preferential binding to N. gonorrhoeae over N. meningitidis were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed. We are persuaded by the Guidelines on this point and adopt the PTO's applicable standard for determining compliance with the written description requirement.

Applying those principles, we first inquire whether Enzo's deposits of the claimed nucleotide sequences of claims 4 and 6 may constitute an adequate description of those sequences. Secondly, we will consider whether the description requirement is met [**17] for all of the claims on the basis of the functional ability of the claimed nucleotide sequences to hybridize to strains of N. gonorrhoeae that are accessible by deposit.

As to the first question, Enzo asserts that the claimed sequences are inherently described by reference to deposits of three sequences that are within the [*965] scope of its claims. Whether reference to a deposit of a nucleotide sequence may adequately describe that sequence is an issue of first impression in this court. In light of the history of biological deposits for patent purposes, the goals of the patent law, and the practical difficulties of describing unique biological materials in a written description, we hold that [HN9] reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of *§ 112*, P 1.

The practice of depositing biological material arose primarily to satisfy the enablement requirement of *§ 112*, P 1. For example, in In re Argoudelis, the patent application claimed [**18] antibiotic compounds that were produced by a microorganism. *58 C.C.P.A. 769, 434 F.2d 1390, 1390, 168 USPQ 99, 100 (CCPA 1970)*. The applicants deposited the microorganism because they could not "sufficiently disclose by written word how to obtain the microorganism starting material from nature." *Id. at 1392, 168 USPQ at 102*. By making the biological material accessible to the public, they enabled the public to make and use the claimed antibiotics. *Id. at 1393, 168 USPQ at 102-03*. In Amgen, we noted the relevance of deposit practice to satisfaction of the enablement requirement but rejected the defendants' argument that a deposit was necessary in that case to satisfy the best mode requirement of *§ 112*, P 1. See *927 F.2d at 1210, 18 USPQ2d at 1024*; see also *In re Lundak, 773 F.2d 1216, 1217, 227 USPQ 90, 92 (Fed. Cir. 1985)* (discussing deposit practice primarily in relation to an enablement rejection and noting that "an accession number and deposit date add nothing to the written description of the invention" in the context of proven availability of a cell line prior to filing date).

Recognizing the importance of biological [**19] deposits to patent practice, the PTO has promulgated rules to address the procedural requirements relating to such deposits, but it has declined to expressly correlate substantive requirements relating to deposits with particular statutory requirements. See Deposit of Biological Materials for Patent Purposes, *53 Fed. Reg. 39,420 39,425* (Oct. 6, 1988) (notice of proposed rules) (codified at *37 C.F.R. Part 1*) ("The rules are not intended to address which requirements of *35 U.S.C. 112* may be met by the making of deposits."). The Office does offer guidance, however, in determining when a deposit may be necessary, such as "where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner." MPEP § 2402 (8th ed. Aug. 2001). The PTO has also issued a regulation stating when a deposit is not necessary, i.e., "if it is known and readily available to the public or can be made or isolated without undue experimentation." *37 C.F.R. § 1.802(b) (2001)*. Inventions that cannot reasonably be enabled by a description in written form in the specification, [**20] but that otherwise meet the requirements for patent protection, may be described in surrogate form by a deposit that is incorporated by reference into the specification. While deposit in a public depository most often has pertained to satisfaction of the enablement requirement, we have concluded that reference in the specification to a deposit may also satisfy the written description requirement with respect to a claimed material.

In this case, Enzo's deposits were incorporated by reference in the specification. A person of skill in the art, reading the [*966] accession numbers in the patent specification, can obtain the claimed sequences from the ATCC depository by following the appropriate techniques to excise the nucleotide sequences from the deposited organisms containing those sequences. *'659* patent, col. 13, ll. 27-36. The sequences are thus accessible from the disclosure in the specification. Although the structures of those sequences, i.e., the exact nucleotide base pairs, are not expressly set forth in the specification, those structures may not have been reasonably obtainable and in any event were not known to Enzo when it filed its application in 1986. See *'659* patent, [**21] col. 3, ll. 40-46 (noting severe time constraints in sequencing DNA). We therefore agree with Enzo that reference in the specification to deposits of nucleotide sequences describe those sequences sufficiently to the public for purposes of meeting the written description requirement.

As the defendants point out, however, Enzo's claims 4 and 6 are not limited to the deposited sequences. Claim 4 is directed to nucleotide sequences that are selected from the group consisting of the three deposited sequences, "discrete nucleotide subsequences thereof . . . mutated discrete nucleotide sequences of any of the foregoing inserts that are within said hybridization ratio and subsequences thereof[,] and . . . mixtures thereof." *'659* patent, col. 28, ll. 31-39. Claim 6 is also similarly directed to the three deposited sequences and subsequences and mutated variations thereof. Id. at ll. 47-56. The specification defines a subsequence non-specifically as a nucleotide sequence "greater than about 12 nucleotides." *'659* patent, col. 3, ll. 29-30. As the deposited sequences are about 850, 850, and 1300 nucleotides long, id. at col. 13, ll. 47-49, there are at least hundreds of subsequences [**22] of the deposited sequences, an unknown number of which might also meet the claimed hybridization ratio. Moreover, Enzo's expert, Dr. Wetmur, stated that "astronomical" numbers of mutated variations of the deposited sequences also fall within the scope of those claims, and that such broad claim scope is necessary to adequately protect Enzo's invention from copyists who could otherwise make a minor change to the sequence and thereby avoid infringement while still exploiting the benefits of Enzo's invention. The defendants assert that such breadth is fatal to the adequacy of the written description. On the other hand, because the deposited sequences are described by virtue of a reference to their having been deposited, it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art. We regard that question as an issue of fact that is best resolved on remand. n2 Because the district court's grant of summary judgment was based on its conclusion that Enzo's deposits could not satisfy the written description requirement as a matter of law, we reverse the district court's grant of summary judgment that claims 4 and 6 are invalid [**23] for failure to meet the written description requirement. On remand, the court should determine whether a person of skill in the art would glean from the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants, and mixtures sufficient to demonstrate possession of the generic scope of the claims.

> n2 We do not address the issue whether the breadth of the claim may implicate other validity issues, such as enablement. Only written description is before us.

We next address the question whether the compositions of the broader genus claims 1-3 and 5 are sufficiently [*967] described to meet the requirements of *§ 112*, P 1, on the basis of Enzo's deposits of three sequences. If those sequences are representative of the scope of the genus claims, i.e., if they indicate that the patentee has invented species sufficient to constitute the genera, they may be representative of the scope of those claims. See *In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973)* [**24] (discussing circumstances in which a species may be representative of and therefore descriptive of genus claims). Because the district court concluded that the deposited sequences were not themselves described, it did not determine whether that description was representative of the genera in those claims. Such determination should be made on remand.

When we addressed a similar issue in Eli Lilly, we determined that a disclosure of the sequence of rat cDNA was not descriptive of the broader invention consisting of mammalian and vertebrate cDNA, although it was a species falling within the scope of those claims. *Eli Lilly, 119 F.3d at 1567-68, 43 USPQ2d at 1405*. In Eli Lilly, the specification and generic claims to all cDNAs encoding for vertebrate or mammalian insulin did not describe the claimed genus because they did not set forth any common features possessed by members of the genus that distinguished them from others. *Id. at 1568, 43 USPQ2d at 1405*. Nor did the specification describe a sufficient number of species within the very broad genus to indicate that the inventors had made a generic invention, i.e., that they had possession [**25] of the breadth of the genus, as opposed to merely one or two such species. *Id.* The PTO has included a hypothetical example based on the facts of Eli Lilly in its Synopsis of Application of Written Description Guidelines in which the description requirement is not met. See Application of Guidelines, Example 17, at 61-64. The PTO has also provided a contrasting example of genus claims to nucleic acids based on their hybridization properties, and has determined that such claims may be adequately described if they hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar. See id., Example 9, at 35-37. Whether the disclosure provided by the three deposits in this case, coupled with the skill of the art, describes the genera of claims 1-3 and 5 is a fact question the district court did not address. On remand, the district court should determine, consistently with the precedent of this court and the PTO's Guidelines, whether one skilled in the art would consider the subject matter of claims 1-3 and 5 to be adequately described, recognizing the significance of the deposits and [**26] the scope of the claims.

Enzo argues that all of the claims are adequately described on another basis, viz., by means of the disclosed correlation of the function of hybridization with the bacterial DNA. In its petition for rehearing, Enzo states as attorney argument that "the description and claiming of biological materials by their affinity to other materials that are clearly identified in the specification and claims (the particular deposited strains of N. gonorrhoeae and N. meningitidis) inherently specifies structure, and is routine in this field." Claim 1 sets forth the deposit numbers of six strains of N. gonorrhoeae to which the claimed nucleotide sequences preferentially hybridize, as well as the deposit numbers of six strains of N. meningitidis that are thereby distinguished. Again, as with the claimed nucleotide sequences, the sequences of the genomic DNA of those bacteria are not disclosed, perhaps because such sequencing would have been unduly burdensome at the time of Enzo's invention. [*968] *'659* patent, col. 3, ll. 40-46 (noting that it would take 3,000 scientists one month to sequence the genome of one strain of N. gonorrhoeae and one strain of [**27] N. meningitidis). However, as those bacteria were deposited, their bacterial genome is accessible and, under our holding today, they are adequately described in the specification by their accession numbers. Because the claimed nucleotide sequences preferentially bind to the genomic DNA of the deposited strains of N. gonorrhoeae and have a complementary structural relationship with that DNA, those sequences, under the PTO Guidelines, may also be adequately described. Although the patent specification lacks description of the location along the bacterial DNA to which the claimed sequences bind, Enzo has at least raised a genuine issue of material fact as to whether a reasonable fact-finder could conclude that the claimed sequences are described by their ability to hybridize to structures that, while not explicitly sequenced, are accessible to the public. Such hybridization to disclosed organisms may meet the PTO's Guidelines stating that functional claiming is permissible when the claimed material hybridizes to a disclosed substrate. That is a fact question. We therefore conclude that the district court erred in granting summary judgment that the claims are invalid for failure [**28] to meet the written description requirement. On remand, the court should consider whether one of skill in the art would find the generically claimed sequences described on the basis of Enzo's disclosure of the hybridization function and an accessible structure, consistent with the PTO Guidelines. If so, the written description requirement would be met.

We next address Enzo's additional argument that the written description requirement for the generic claims is necessarily met as a matter of law because the claim language appears in ipsis verbis in the specification. We do not agree. Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement.

One may consider examples from the chemical arts. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its function of lessening inflammation of tissues fails to distinguish any steroid [**29] from others having the same activity or function. Similarly, the expression "an antibiotic penicillin" fails to distinguish a particular penicillin molecule from others possessing the same activity. [HN10] A description of what a material does, rather than of what it is, usually does not suffice. *Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.* The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Id.*

In Eli Lilly, we were faced with a set of facts in which the words of the claim alone did not convey an adequate description of the invention. *Id. at 1567, 43 USPQ2d at 1405.* In such a situation, regardless whether the claim appears in the original specification and is thus supported by the specification as of the filing date, *§ 112*, P 1 is not necessarily met. See Guidelines at 1100 (noting Eli Lilly's clarification of the "original claim" doctrine in situations in which the name of the claimed material does not convey sufficient identifying information). If a purported description of an invention does not meet the requirements of the statute, the fact that it appears [**30] as an original claim or in the specification does [*969] not save it. A claim does not become more descriptive by its repetition, or its longevity.

Inasmuch as *§ 112*, P 1 requires such description, we are not persuaded by Enzo's argument that, because the specification indicated that Enzo "possessed" the claimed invention by reducing three sequences within the scope of the claims to practice, Enzo necessarily described the invention. It is true that in Vas-Cath, we stated: [HN11] "The purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath, 935 F.2d at 1563-64, 19 USPQ2d at 1117.* That portion of the opinion in Vas-Cath, however, merely states a purpose of the written description requirement, viz., to ensure that the applicant had possession of the invention as of the desired filing date. It does not state that possession alone is always

sufficient to meet that requirement. Furthermore, in Lockwood v. American Airlines, Inc., we rejected [**31] Lockwood's argument that "all that is necessary to satisfy the description requirement is to show that one is 'in possession' of the invention." *107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997)*. Rather, we clarified that the written description requirement is satisfied by the patentee's disclosure of "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." *Id.*

The articulation of the written description requirement in terms of "possession" is especially meaningful when a patentee is claiming entitlement to an earlier filing date under *35 U.S.C. § § 119 or 120*, in interferences in which the issue is whether a count is supported by the specification of one or more of the parties, and in ex parte applications in which a claim at issue was filed subsequent to the application. See *Vas-Cath, 935 F.2d at 1560, 19 USPQ2d at 1114* (describing situations in which the written description requirement may arise); *Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985)* (noting, in the context of claiming [**32] entitlement to the priority date of an earlier application, that the written description requirement is met if "the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter"). Application of the written description requirement, however, is not subsumed by the "possession" inquiry. A showing of "possession" is ancillary to the statutory mandate that "the specification shall contain a written description of the invention," and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention. After all, as indicated above, one can show possession of an invention by means of an affidavit or declaration during prosecution, as one does in an interference or when one files an affidavit under *37 C.F.R. § 1.131* to antedate a reference. However, such a showing of possession alone does not cure the lack of a written description in the specification, as required by statute.

Similarly, we conclude that proof of a reduction to practice, absent an adequate description in the specification of what is [**33] reduced to practice, does not serve to describe or identify the invention for purposes of *§ 112*, P 1. [HN12] As with "possession," proof of a reduction to practice may show priority of invention or allow one to antedate a reference, but it does not by itself provide a written description in the patent specification. We are thus not persuaded [*970] by Enzo's argument, relying on the PTO's Guidelines, that its disclosure of an actual reduction to practice is an important "safe haven" by which it has demonstrated compliance with the description requirement. The Guidelines state:

> [HN13] Actual reduction to practice may be crucial in the relatively rare instances where the level of knowledge and level of skill are such that those of skill in the art cannot describe a composition structurally, or specify a process of making a composition by naming components and combining steps, in such a way as to distinguish the composition with particularity from all others.

Guidelines, *66 Fed. Reg. at 1101*. For biological inventions, for which providing a description in written form is not practicable, one may nevertheless comply with the written description requirement by publicly [**34] depositing the biological material, as we have held today. That compliance is grounded on the fact of the deposit and the accession number in the specification, not because a reduction to practice has occurred. Such description is the quid pro quo of the patent system; the public must receive meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.

CONCLUSION

For the foregoing reasons, we conclude that the district court erred in granting summary judgment that the claims of the *'659* patent are invalid for failure to meet the written description requirement of *§ 112*, P 1. While the district judge clearly understood and correctly applied this court's existing precedent, we nevertheless reverse because this case has taken us into new territory and we have held, as a matter of first impression, that reference in a patent specification to a deposit of genetic material may suffice to describe that material. We therefore remand for further resolution consistent with this opinion.

REVERSED and REMANDED

ON PETITION FOR REHEARING

ORDER

A petition for rehearing was filed by the plaintiff-appellant, and a response thereto [**35] was invited by the court and filed by the defendants-appellees. The United States Patent and Trademark Office and Fish & Richardson P.C. filed briefs as amici curiae. This matter was referred first to the merits panel that heard this appeal, which vacated its earlier decision and prepared a revised decision for issuance. Thereafter, at the request

of a non-panel judge, an en banc poll was conducted concerning whether the appeal ought to be heard en banc. The poll failed. Circuit Judges RADER, GAJARSA, and LINN would have heard the appeal en banc.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for rehearing is granted as set forth in the panel opinion issued concurrently with this order.

LOURIE, Circuit Judge, with whom NEWMAN, Circuit Judge, joins, filed an opinion concurring in the court's decision not to hear the case en banc.

NEWMAN, Circuit Judge, filed an opinion concurring in that decision.

DYK, Circuit Judge, filed an opinion concurring in that decision.

RADER, Circuit Judge, with whom GAJARSA and LINN, Circuit Judges, join, filed an opinion dissenting from that decision.

[*971] LINN, Circuit Judge, with whom RADER and GAJARSA, [**36] Circuit Judges, join, filed an opinion dissenting from that decision.

July 15, 2002 Date

CONCURBY: LOURIE; NEWMAN; DYK

CONCUR: LOURIE, Circuit Judge, with whom NEWMAN, Circuit Judge, joins, concurring in the court's decision not to hear the case en banc.

I agree that the court correctly declined to hear this case en banc.

First, it is important to note that the earlier panel majority, in response to the petition for rehearing, has reversed its earlier decision. Taking the case en banc would therefore delay and hence frustrate the remand of the case solely for the purpose of revising written description law. That law is sound and does not need revision, at least as proposed by the dissents.

The dissenters believe that the written description requirement is simply a requirement for enablement. With all due respect, that is incorrect. The complete statutory provision is as follows:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly [**37] connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, P 1 (1994) (emphasis added). I read the statute so as to give effect to its language. The statute states that the invention must be described. That is basic patent law, the quid pro quo for the grant of a patent. Judge Rader notes that historically the written description requirement served a purpose when claims were not required. While that may be correct, when the statute began requiring claims, it was not amended to delete the requirement; note the comma between the description requirement and the enablement provision, and the "and" that follows the comma. Judge Rich, whom Judge Rader cites, was in fact one of the earliest interpreters of the statute as having separate enablement and written description requirements. *In re Ruschig, 54 C.C.P.A. 1551, 379 F.2d 990, 995-996, 154 USPQ 118, 123 (C.C.P.A. 1967)*; *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)*. The basic requirement to describe one's invention was recently emphasized [**38] as an independent patentability requirement by the Supreme Court in Festo:

> In addition, the patent application must describe, enable, and set forth the best mode of carrying out the invention. *§ 112* (1994 ed.). These latter requirements must be satisfied before issuance of the patent, for exclusive patent rights are given in exchange for disclosing the invention to the public. See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150-151, 103 L. Ed. 2d 118, 109 S. Ct. 971.* What is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue.

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 122 S. Ct. 1831, 1840, 152 L. Ed. 2d 944 (2002) (emphases added).

It is said that applying the written description requirement outside of the priority context was novel until several years ago. Maybe so, maybe not; certainly such a holding was not precluded by statute or precedent. New interpretations of old statutes in light of new fact situations occur all the time. I believe these issues have arisen in recent years for the same reason that more

doctrine of equivalents [*972] issues are in the courts, [**39] viz., because perceptions that patents are stronger tempt patent owners to try to assert their patents beyond the original intentions of the inventors and their attorney. That is why the issues are being raised and that is why we have to decide them. Claims are now being asserted to cover what was not reasonably described in the patent.

Moreover, the dissenters would limit the requirement, to the extent that they credit the written description portion of the statute as being a separate requirement at all, to priority issues. The statute does not say "a written description of the invention for purposes of policing priority." While it has arisen primarily in cases involving priority issues, Congress has not so limited the statute, and we have failed to so limit it as well. As for the lack of earlier cases on this issue, it regularly happens in adjudication that issues do not arise until counsel raise them, and, when that occurs, courts are then required to decide them. Even now, a written description issue should not arise unless a patentee seeks to have his claims interpreted to include subject matter that he has not adequately disclosed in his patent. Although it is true that the [**40] written description requirement has been applied rigorously in some recent cases, I do not believe that any of those cases were decided wrongly. The losing patents (or applications) involved did not adequately disclose what was claimed: a particular ratio of variables, *Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1327, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000)*; a sofa with controls other than on the console, *Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1480, 45 USPQ2d 1498, 1503-1504 (Fed. Cir. 1998)*; a cup other than a conical cup, *Tronzo v. Biomet, Inc., 156 F.3d 1154, 1159-60, 47 USPQ2d 1829, 1833-34 (Fed. Cir. 1998)*; human insulin cDNA, *Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1567, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997)*; or beta-interferon, *Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993)*. Interpretation of written description as this court has done furthers the goal of the law to have claims commensurate in scope with what has been disclosed to the public.

I believe that the dissenters miss the point in seeing this case as involving [**41] an original claim or in ipsis verbis issue. There is no question that an original claim is part of the specification. That was the question answered in the affirmative by *In re Gardner, 480 F.2d 879, 178 USPQ 149 (C.C.P.A. 1973)*, in which the CCPA found compliance with the written description requirement over the objection of the PTO Commissioner, who argued that an original claim should not be considered part of the written description unless the specification was amended to contain the subject matter of the original claim. However, the question here is whether the disclosure, as an original claim, or in the specification, * adequately describes the invention. It is incorrect that the mere appearance of vague claim language in an original claim or as part of the specification necessarily satisfies the written description requirement or shows possession of a generic invention.

> Not only are we not entitled to ignore the statutory written description requirement, but our court has not. Earlier cases also upheld a separate written description requirement, and the fact that they may have pertained to priority disputes does not vitiate their basic requirement [**42] to disclose one's invention. *Section 112*, paragraph [*973] 1, does not limit itself to priority disputes. I thus believe it is incorrect, as Judge Rader states, that our cases have limited the written description/new matter doctrine to priority protection. Opinions explain the decisions on the issues that come before them on the facts presented; those cases have not expressly limited the written description requirement to priority issues, and in fact they emphasize that the requirement arises in a "variety of situations." *In re Wright, 866 F.2d 422, 424, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989)*. Any language seemingly appearing to limit the language to priority issues does so because it addresses a priority issue that was before it. Other broad language is not binding holding on different facts and raising different issues. Courts do not, or should not, purport to write treatises on the law, outlining all aspects of a statute that comes before them. They decide issues raised in light of the decision being reviewed.

> * Enzo's claim 1 is actually not an original claim. It was amended to include language appearing in the original specification and it thus appears in ipsis verbis in the specification.

[**43]

Moreover, even if written description is related to and overlaps with "new matter," so what? One can fail to meet the requirements of the statute in more than one manner, and in any event the case cited as equating those two requirements in fact distinguishes *§ § 112 and 132* as concerning: (1) claims not supported by the disclosure; and (2) the prohibition of new matter to the

disclosure, respectively. *In re Rasmussen, 650 F.2d 1212, 1214-15, 211 USPQ 323, 326 (C.C.P.A. 1981).* Rasmussen states that "the proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure, therefore, is *§ 112*, first paragraph, not *§ 132*." Id.

In addition, we do not "elevate 'possession' to the posture of a statutory test of patentability." Rather, the opinion refines the "possession" test for circumstances such as these in which the inventors showed possession of a species of the invention by reference to a deposit, but may not have described what else within the scope of the claims they had possession of. While "possession" is a relevant factor in determining whether an invention is described, it is only a criterion [**44] for satisfying the statutory written description requirement. Showing possession is not necessarily equivalent to providing a written description.

Judge Rader's dissenting opinion cites authors who disapprove of our decisions. While views of knowledgeable and objective commentators are surely of interest to this court, we should not interpret the law based on taking polls of discontented writers. Our commission is to apply the law to the facts and attempt to explain the reasons for our decisions. Critical articles may be written by those who have lost a case, or those who are skilled in a particular technology or not, or those who have little practical experience or who are seasoned experts. While Judge Rader cites articles critical of Lilly, others are favorable. Not surprisingly, an author from Eli Lilly took a positive view of the case. See Mark J. Stewart (patent associate at Eli Lilly), Note, *The Written Description Requirement of 35 U.S.C. § 112(1): The Standard After* Regents of the University of California v. Eli Lilly & Co., *32 Ind. L. Rev. 537, 563 (1999)* ("The holding in Lilly actually avoided a disaster that would have [**45] crippled the biotechnology industry. The enormous amount of time and money companies spend to study DNA and protein variants, to clone homologous genes and protein family members, and to mine databases would no longer be justified had the court found the written description in '525 adequate.").

Other authors support a robust written description requirement and point out the benefits of such a requirement to the public. [*974] See, e.g., Scott A. Chambers, *"Written Description" and Patent Examination Under the U.S. Patent and Trademark Office Guidelines*, IP Litigator, Sept.-Oct. 2000, at 9, 10 ("Thus, the Federal Circuit's present interpretation of the written description requirement maintains the vitality of the U.S. patent system and provides disclosures that others can build on. By suggesting that disclosure of the structure or actual sequence of complex chemical entities may sometimes be required, the Federal Circuit may have advanced the goal of the patent system to actually put the claimed invention into the hands of the public."); Margaret Sampson, *The Evolution of the Enablement and Written Description Requirements under 35 U.S.C. § 112 in the* [**46] *Area of Biotechnology, 15 Berkeley Tech. L. J. 1233, 1260-61 (2000)* ("Without a heightened written description requirement, inventors could receive patent rights to sequences of which they have no knowledge, in organisms with which they have never worked. . . . Therefore, the Federal Circuit's approach to the written description requirement in the area of biotechnology has prevented nucleotide sequence claims from becoming a Pandora's box that the patent law is unable to control."). In any event, we decide cases as they come to us, based on the arguments raised, the decisions below, the law, the facts, and our best efforts, not based on occasional journal articles.

> Since some of the cases implicated by this issue are in the biotech field, I should point out that, among the problems in comprehension of the issues in a biotech context is that a functional description of DNA does not indicate which DNA has been invented. And simply acknowledging the presence of a DNA that serves a particular function, whose existence has been postulated since, perhaps, Mendel, plus a general process for finding it, is not a description of the DNA. It is a research plan at best, [**47] and does not show "possession" of any invention.

Still, in terms of the more practical aspects of complying with the statute, meeting the description requirement is the first task in drafting a patent application. Enabling one of skill in the art to make and use the invention is a separate requirement. To interpret the written description requirement only as an enablement provision is to let the tail wag the dog. Perhaps there is little difference in electrical and mechanical inventions between describing an invention and enabling one to make and use it, but that is not true of chemical and chemical-like inventions.

Enzo's patent claimed a genus of chemical-like materials (a sequence of nucleic acids is of a chemical nature -- note the claims begin with "a composition"). Although one may envision a general concept, what one usually does first in making or isolating a chemical or chemical-related invention is to obtain a specific material or materials. One then broadens the concept to extend it as far as one envisions that other materials will have the same utility and can be similarly made. That broadened

concept becomes the genus in a patent application that is both the broadest [**48] statement constituting a written description and usually claim 1. One then elaborates to fill in the genus with representative examples of compounds or substances that fall within the genus. That is part of the written description needed to support the generic claim. Then, one tells how to make the materials, and then how to use them. That is enablement, separate in concept from describing what the invention is. The idea that there is no requirement in the statute to describe one's new invention (aside from the fact that the language of the statute contains one) separate from the requirement to enable one to make and use it is not correct. Disclosure [*975] is the first role of a patent. One must first state what one's invention is. That is quite different from telling how to make and use it.

Some commentators have had difficulty in understanding how one may have enabled an invention, but not described it. They believe they must coincide. As an example of how the written description and enablement provisions differ in chemistry, however, one may readily have enabled the making of an invention, but still not have described it. For example, a propyl or butyl compound may be made by [**49] a process analogous to a disclosed methyl compound, but, in the absence of a statement that the propyl and butyl compounds are part of the invention, they have not been described and they are not entitled to a patent (I make no implication here about coverage under the doctrine of equivalents). See *In re Di Leone, 58 C.C.P.A. 925, 436 F.2d 1404, 1405 n.1, 168 USPQ 592, 593 n.1 (C.C.P.A. 1971)* ("Consider the case where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described."). This is surely part of the recent history of some biotechnology patents.

In sum, we have evolved a consistent body of law over a number of years, based on the statute and basic principles of patent law. I see no reason to hear this case en banc and rewrite the statute.

NEWMAN, Circuit Judge, concurring in the denial of rehearing *en banc*.

I join Judge Lourie's statement, and write separately to emphasize my concern with the position of the dissent concerning the law of written description. The [**50] description of the invention has always been the foundation of the patent specification. It sets forth what has been invented, and sets boundaries of what can be claimed. The theory of the dissent that a description of the invention is not needed in order to support the claims, but serves only to antedate prior art or establish priority in an interference, is a dramatic innovation in the theory and practice of patents. It has never been the sole purpose of the description requirement, and negates not only the logic but also the history of patent practice. The dissent's citation of cases in which the description of the invention has been relied on to antedate references and in interference contests reinforces, not reduces, the role of the description of the invention in establishing what has been invented.

The dissent argues that the subject matter that is intended to be patented need not be described, as long as it is enabled. Undoubtedly, in many patents these requirements are met by the same information content. And the special case of the biological deposit is a method of complying with the statutory requirements, as the panel now confirms; this expedient implements the statute [**51] for this special subject matter, but does not change it. It is not the law that the description of the invention serves only to establish priority, to be invoked only when priority is at issue. The invention that is covered by the claims must be described as well as enabled, as the statute has always required.

DYK, Circuit Judge, concurring in the court's decision not to hear the case en banc.

The opinions of Judges Newman, Lourie, Rader, and Linn concerning the denial of en banc rehearing raise important and interesting questions, including questions concerning the correctness of our earlier [*976] decision in *Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997)*, cert. denied, *523 U.S. 1089 (1998)*, that may someday warrant the court's en banc attention. Given the panel's decision on rehearing, remanding for further consideration by the district court, this is not the appropriate occasion for en banc review. The court will also benefit from further percolation of these issues before they are addressed by the full court.

DISSENTBY: RADER; LINN

DISSENT: RADER, Circuit Judge, with [**52] whom GAJARSA and LINN, Circuit Judges, join, dissenting from the court's decision not to hear the case en banc.

The tortuous path of this case shows the perils of ignoring the statute and over thirty years of consistent written description case law n1 . The first version of this opinion, *Enzo Biochem, Inc. v. Gen-Probe, Inc., 285 F.3d 1013, 62 USPQ2d 1289 (Fed. Cir. 2002)*, purported to invalidate a patent because the inventor had not shown "possession of the invention" for written description. See, *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1564, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)*. As this court

now acknowledges, an inventor can hardly show possession of an invention better than by depositing the invention in an internationally recognized repository. This court corrects part of the mistake of Enzo I. Yet the court still remands to the district court to reexamine the written description requirement. Because the written description requirement as created and applied for thirty years does not apply to this case, I would grant en banc review and correct the rest of this court's misapplication of the description requirement.

> n1 An appendix at the close of this opinion will briefly explicate all written description cases from its creation in 1967 in the Court of Customs and Patent Appeals to the present. This appendix shows that only two cases, this ENZO case and the 1997 LILLY case have purported to apply the doctrine outside its purpose and function.

[**53]

Statute

Because the greater mistake in this case is misapplication of this court's written description case law, this opinion devotes only a few paragraphs to the statutory interpretation question. The United States' brief as *amicus curiae* in support of rehearing *en banc* states concisely this Enzo opinion's disregard for the statute:

> A straightforward reading of the text of *section 112* suggests that the test for an adequate written description is whether it provides enough written information for others to make and use the invention. The statute provides that the "specification shall contain a written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." *35 U.S.C. § 112* P 1. Thus, an adequate written description assures that others can "make and use" the invention. n2

If it is possible to characterize disregard of statutory text as a secondary mistake, this case fits that classification. The more important problem is disregard for the case law that originated the written description requirement and applied it for over thirty years. [**54]

> n2 This court rejected the "straightforward reading" of the statute in Vas-Cath because the written description (WD) doctrine was a priority control, not the general disclosure doctrine of enablement. See, *Vas-Cath, 935 F.2d 1555.* Within the proper purpose of WD, Vas-Cath makes sense. When applied outside the priority context as a general disclosure doctrine, however, WD cannot depart from the enablement test without replacing it. Thus, the United States advocates application of the statutory standard of enablement.

[*977] Origin and History of the Written Description Requirement

The words "written description" first appeared in the *Patent Act of 1793. At* that time, of course, patents did not require claims but only a written description sufficient "to distinguish [the invention] from all other things before known or used." In *Evans v. Eaton, 20 U.S. 356, 5 L. Ed. 472 (1822)*, the Supreme Court construed the description language to require applicants to enable their [**55] inventions and to provide the notice function of claims:

> [After enablement,] the other object of the specification is to put the public in possession of what the party claims as his own invention, so as to ascertain if he claims any thing that is in common use, or is already known . . .

Id. at 433. In later enactments, this notice function was assigned to claims, leaving enablement as the only purpose of the "written description" language. As noted in the United States' brief, the modern descendant of the 1793 phrase still requires only a written description "in such . . . terms as to enable [the invention]." *35 U.S.C. § 112.* In J.E.M. Ag. Supply, the Supreme Court acknowledged only enablement as the disclosure *quid pro quo* of the *Patent Act*: "In addition [to novelty, utility, and nonobviousness], to obtain a utility patent, a breeder must describe the plant with sufficient specificity to enable others to 'make and use' the invention after the patent term expires." *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 122 S. Ct. 593, 604, 151 L. Ed. 2d 508 (2001).* Reading the statute, [**56] the Supreme Court correctly found no general disclosure requirement in title 35 other than enablement. n3

> n3 In Festo, the Supreme Court mentions a description requirement separate from enablement. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 122 S. Ct. 1831, 1840, 152 L. Ed. 2d 944 (2002).* This

> listing of doctrines, however, did not endorse any departure from this court's case law for more than thirty years.

Before 1967, this court's predecessor, the United States Court of Customs and Patent Appeals also did not differentiate written description from enablement. In 1966, that predecessor court wrote in detail about *section 112*, paragraph 1, and found only two requirements -- enablement (the A requirement under Judge Rich's terminology) and best mode (the B requirement). *In re Gay, 50 C.C.P.A. 725, 309 F.2d 769, 772, 135 USPQ 311, 315 (CCPA, 1962).*

In 1967, the Court of Customs and Patent Appeals first separated a new written description (WD) requirement from [**57] the enablement requirement of *§ 112*. The reason for this new judge-made doctrine needs some explanation. Every patent system must have some provision to prevent applicants from using the amendment process to update their disclosures (claims or specifications) during their pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of invention. Priority - always a vital issue in patent prosecution procedures -- often determines entitlement to an invention. Before 1967, the United States Patent Office and the Court of Customs and Patent Appeals used a "new matter" rejection to ensure that applicants did not update their disclosures after the original filing date of the application. This "new matter" rejection had a statutory basis: "No amendment shall introduce new matter into the disclosure of the invention." *35 U.S.C. § 132.*

In 1967, in *In re Ruschig, 54 C.C.P.A. 1551, 379 F.2d 990, 154 USPQ 118 (CCPA 1967)*, this court's predecessor created for the [*978] first time a new WD doctrine to enforce priority. In [**58] the context of a new claim added "about a year after the present application was filed," the Ruschig court sought to determine "whether [the new] claim 13 is supported by the disclosure of appellants' application." *Id. at 991.* Rather than use *§ 132*, however, Ruschig assigned the role of policing priority to *§ 112*. As a technical matter, the Court of Customs and Patent Appeals distinguished between adding new matter to the specification and adding new matter to the claims. Under PTO practice, new matter in the claims would draw a *§ 132* rejection of the claims; new matter in the specification would draw a *§ 132* objection to the addition. The Ruschig court, for the first time, decided to treat the objection alone as a *§ 132* matter. To deal with new matter in the claims, the court calved a new WD doctrine out of the *§ 112* enablement requirement n4 . As long as the new WD doctrine applied according to its original purpose as an identical twin of the *§ 132* new matter doctrine, these technical distinctions were of little practical consequence.

> n4 As a matter of integrity to the statute, the Ruschig distinction has a major problem, namely the language of *§ 132* embraces both new matter rejections of amended claims and new matter objections to amended specifications. Both claims and the rest of the specification are part of the patent "disclosure" within the terms of *§ 132*. See, e.g., *In re Frey, 35 C.C.P.A. 970, 166 F.2d 572, 575, 77 USPQ 116, 119 (CCPA 1948)* ("Certainly the [claim] is a disclosure of itself."). Moreover implicit in the judicial creation of a new WD requirement is the incorrect assumption that the *Patent Act* had no remedy for new matter in claims before 1967. In fact, *§ 132* embraces both new matter rejections and objections.

[**59]

In any event, the WD doctrine, at its inception had a very clear function - preventing new matter from creeping into claim amendments. Judge Rich, the author of Ruschig, often reiterated the purpose of WD. For instance in the case of *In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976)*, the Court of Customs and Patent Appeals confronted a priority issue:

> The dispositive issue under this heading is whether appellants' parent and Swiss applications comply with *35 U.S.C. § 112*, first paragraph, including the description requirement, as to the subject matter of these claims. If they do, these claims are entitled to the filing dates of the *parent* application . . . . [A] right of foreign *priority* in appellants' Swiss application will antedate Pfluger 1966 and remove it as prior art against the claims.

Id. at 261 (emphasis added). In resolving this question, Judge Rich stated again the purpose of WD: "The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter *later* claimed by him." *Id. at 262* [**60] (emphasis added). In sum, WD was a new matter doctrine, a priority policeman.

Returning to the history of WD, after 1967, the PTO continued to use new matter rejections under *§ 132*, but also embraced the coterminous written description analysis. Thus, for many years, the PTO rejected priority errors in claims under both *§ 132* and *§ 112*.

In 1981, the Court of Customs and Patent Appeals noted that the two rejections were interchangeable: "This court, has said that a rejection of an amended claim under *§ 132* is equivalent to a rejection under *§ 112*, first paragraph." *In re Rasmussen, 650 F.2d 1212, 1214, 211 USPQ 323, 325 (CCPA, 1981)* (emphasis added). To avoid confusion between new matter rejections and objections, the court chose to eliminate the *§ 132/ § 112* rejections and to use *§ 112* for new matter rejections (claims): "The proper basis for rejection of a claim amended to recite elements [*979] thought to be without support in the original disclosure, therefore, is *§ 112*, first paragraph, not *§ 132*." Id. The purpose of the doctrine did not change. As the sentence above states explicitly, the *§ 112* doctrine, like its corollary *§ 132*, policed priority, [**61] nothing more. At no time did either the CCPA or the Federal Circuit purport to apply the equivalent new matter/written description rejections to original claims or other claims without priority problems. See, e.g., *In re Koller, 613 F.2d 819, 823, 204 USPQ 702, 706 (CCPA 1980)* ("Original claims constitute their own description."); *In re Gardner, 475 F.2d 1389, 1391, 177 USPQ 396, 397 (CCPA 1973)* ("Claim 2, which apparently was an original claim, in itself constituted a description in the original disclosure . . . . Nothing more is necessary for compliance with the description requirement . . . ."). WD, the equivalent of the statutory new matter doctrine, simply has no application to claims without priority problems.

The Federal Circuit continued to follow this binding precedent. See, e,g, *Vas-Cath, 935 F.2d at 1560* ("The question raised by these situations is most often phrased as whether the application provides 'adequate support' for the claim(s) at issue; it has also been analyzed in terms of 'new matter' under *35 U.S.C. § 132*."); *In re Wright, 866 F.2d 422, 424, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989)* [**62] ("When the scope of a claim has been changed by amendment in such a way as to justify an assertion that it is directed to a *different invention* than was the original claim, it is proper to inquire whether the newly claimed subject matter was *described* in the patent application when filed as the invention of the applicant. That is the essence of the so-called 'description requirement' of *§ 112*, first paragraph.") (emphases added); n5 *In re Kaslow, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983)*. In fact, this Circuit's test for written description required assessment of the specification to check "later claimed subject matter." *Id. at 1375* ("The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the *later* claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language.") (emphasis added). In fact, this standard emphasizes that WD does not examine the specification for "literal support" of the claim language unless [**63] priority is in question. In any event, this Circuit did not apply WD to claims without priority problems because the doctrine had no purpose beyond policing priority. n6

n5 In Wright, Judge Rich mentions that WD arises in "a variety of situations." Id. Of course, this observation is an accurate description of the priority issue. Priority arises in the context of a *§ 102(b)* rejection, see, e.g., *In re Ruschig, 379 F.2d at 991*, a *§ 119* issue, see, e.g., *In re Wertheim, 541 F.2d at 261*, a *§ 120* issue, see, e.g., *Kennecott Corp. v. Kyocera Int'l., Inc., 835 F.2d 1419, 1421 (Fed. Cir. 1987)* ("The incorporation of the requirements of *section 112* into *section 120* ensures that the inventor had possession of the later-claimed invention on the filing date of the earlier application."), and a *§ 102(g)* interference, see, e.g., *Fiers v. Revel, 984 F.2d at 1169*, to mention just a few of the variety of situations in which priority arises. This statement hardly justifies applying WD outside its purpose as a test for sufficiency of disclosure. [**64]

n6 Again, the appendix at the close of this opinion shows that the Federal Circuit uniformly applies WD to police priority. Only the LILLY and this ENZO opinion purport to apply it as a general disclosure requirement in place of enablement.

The deviation from thirty years of precedent

In 1997, for the first time, this court purported to apply WD as a general disclosure [*980] doctrine in place of enablement, rather than as a priority doctrine. *Regents of the Univ. of Cal. v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997)*. In Lilly, this court found that the '525 patent specification does not provide a WD of human insulin cDNA despite the disclosure of a general method of producing human insulin cDNA and a description of the human insulin A and B chain amino acid sequences that cDNA encodes.

119 F.3d at 1567. In the words of the court, "a description that does not render a claimed invention obvious does not sufficiently describe that invention for purposes of *§ 112*, P 1." Id. At another point, the court stated: "An adequate written description [**65] of a DNA . . . 'requires a precise definition, such as by structure, formula, chemical name, or physical properties . . . .'" *Id. at 1566* (quoting *Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993)*). In sum, the Lilly opinion does not test a later claim amendment against the specification for priority, but asserts a new free-standing disclosure requirement in place of the statutory standard of enablement. Based on the absence of a nucleotide-by-nucleotide recitation in the specification of the human insulin cDNA, the court determined that the applicant had not adequately described the invention. For the first time, this court purported to apply WD without any priority question. But see, *Kaslow, 707 F.2d at 1375* ("rather than the presence or absence of literal support in the specification for the claim language."). Even accepting that WD can be isolated as a separate requirement from enablement in *§ 112*, P 1, the words "written description" hardly prescribe a standard that requires nucleotide-by-nucleotide disclosure.

Under the correct written description test, one of skill in the art would have recognized [**66] that the '525 patent in Lilly had no new matter or priority problems. In terms of the statutory test for adequacy of disclosure, the patent disclosure undoubtedly warranted rejection for lack of enablement. Under the Wands test for enablement, *858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)*, the inventor certainly did not show one of skill in the art how to make human insulin cDNA. n7 Moreover the patent claimed vertebrate insulin cDNA - a category ranging from fish to humans - again claims whose scope far exceeds the patent's enabling disclosures. In fact, the patent disclosure only revealed that the inventor had enabled cloning of rat insulin. Instead of invalidating under the statutory test for adequacy of disclosure, i.e., enablement, the Lilly court purported to create a new doctrine for adequacy of disclosure that it labeled incorrectly "written description." As noted, from its creation through thirty years of application, WD had never been a free-standing substitute for enablement.

> n7 *U.S. Pat. No. 4,652,525*, the patent at issue in Lilly, was filed in 1983, but claimed priority to a parent filed in 1977. In 1977, biotechnology was still in its infancy. In fact, the Maxam and Gilbert method of sequencing DNA was just published in 1977. Cloning in that era was, at a minimum, unpredictable and would have required vast amounts of experimentation to accomplish. Therefore, the patent's prophetic disclosure of human insulin cDNA hardly enabled its production as claimed. Instead of pursuing this obvious avenue of rejection, the Federal Circuit reached out beyond the statute and the case law to create a new general disclosure test.

[**67]

Although it should not be necessary, a brief defense of the statutory standard for adequate disclosure shows the flaws of the new form of WD. Enablement already requires inventors to disclose how to make (reproduce, replicate, manufacture) and how to use the invention (by definition rendering it a "useful art"). Therefore, [*981] because the competitor can make the invention, it can then acquire the DNA sequence or any other characteristic whenever it desires. Meantime the competitor can use, exploit, commercialize (outside the patent term) or improve upon and design around (within the patent term) as much of the invention as it cares to make. In other words, the statutory standard for sufficiency of disclosure serves masterfully the values of the patent system.

Even after Lilly, the Federal Circuit -- in all other WD cases before this Enzo case -- applied priority principles, declining to assert the doctrine as a general test for adequacy of disclosure. See, e.g., *Union Oil Co. of Cal. v. Atlantic Richfield Co., 208 F.3d 989, 54 USPQ2d 1227 (Fed. Cir. 2000)*. One of those opinions analyzes WD with particular care:

> The written description [**68] requirement and its corollary, the new matter prohibition of *35 U.S.C. § 132*, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date. When the applicant adds a claim or otherwise amends his specification after the original filing date, as Brandon did in this case, the new claims or other added material must find support in the original specification.

TurboCare Div. Of Demag Delaval Turbomachinery Corp. v. General Elec. Co., 264 F.3d 1111, 1118, 60 USPQ2d 1017, 1022 (Fed. Cir. 2001).

In sum, the written description language has been in the statute since 1870, yet only since 1967 has case law

separated it from enablement. The separation itself is not disruptive of the patent system, however, because the doctrine operated solely to police priority. Indeed, with the exception of Lilly and this Enzo case, this court and its predecessor have only applied the doctrine within the limits of its origin as an "equivalent" or "corollary" of *35 U.S.C. § 132*, the new matter section.

Enzo and written description

The record in this case shows [**69] that no priority issues remain to invoke WD. The inventor in this case amended the original claims in response to the examiner's request to place the selective hybridization steps in the claims. Thus, the amendments were all narrowing - meaning the applicant added no new matter to the claims by amendment. Instead, the applicant copied material from the original specification into the original claims. By definition, this case presents no new matter or priority issues requiring application of the original WD doctrine. The original specification contained all of the subject matter included in the inventor's claims. For this reason, the panel misapplies *§ 112*, P 1 by remanding on the question of WD. See, slip op. at 17 ("On remand, the court should consider whether one of skill in the art would find the generically claimed sequences described on the basis of Enzo's disclosure of the hybridization function and an accessible structure, consistent with the PTO Guidelines. If so, the written description requirement would be met."). If any *§ 112*, P 1 questions remain, they are questions of the sufficiency of disclosure, an enablement question. Instead, the panel, relying on Lilly [**70] , advocates applying WD "regardless whether the claim appears in the original specification and is thus supported by the specification as of the filing date." Id. at 18. To the contrary, WD has no such application consistent with the statute and the case law.

Why does this matter?

As both Lilly and this case show, the aberrant form of WD requires far more [*982] specific disclosure than enablement. n8 Because the Lilly application of *§ 112*, P 1 requires a far more demanding disclosure, defendants will have no need to invoke enablement, but will proceed directly to the more demanding Lilly *§ 112*, P 1 requirements. Thus, the new breed of WD evident in Lilly and this case threatens to further disrupt the patent system by replacing enablement - the statutory test for adequate disclosure. See, Rai, Arti, "Intellectual Property Rights in Biotechnology: Addressing New Technology" *34 Wake Forest L. Rev. 827, 834-35 (Fall, 1999)* ("Thus in [Lilly] . . . the CAFC broke new ground by applying the written description requirement not only to later-filed claims but also to claims filed in the original patent. . . . T]he Lilly court used the written [**71] description requirement as a type of elevated enablement requirement."); Mueller, Janice M., "The Evolving Application of the Written Description Requirement to Biotechnological Inventions" *13 Berkeley Tech. L.J. 615, 617 (Spring 1998)* ("The Lilly decision establishes uniquely rigorous rules for the description of biotechnological subject matter that significantly contort written description doctrine away from its historic origins and policy grounding. The Lilly court elevates written description to an effective 'super enablement' standard . . ..").

n8 "Conflicts in Federal Circuit Patent Law Decisions," The Federal Circuit Bar Journal, Vol. 11, no. 3, p. 723, chronicles this circuit's primary conflicts. Listed first as the leading conflict is "I. The Written Description Requirement of *§ 112*, First Paragraph." Id. at 725-34. The article notes: "The Federal Circuit has not provided clear and consistent rules for determining precisely what type of disclosure is sufficient to comply with the *§ 112* written description requirement." Id. at 725. The article then notes three separate tests for measuring compliance with *§ 112*, P 1. For instance, "the strictest approach requires the written description to delineate all of the claimed elements. " Id.

[**72]

Furthermore, the Supreme Court repeatedly cautioned against the disruption of the settled expectations of the inventing community. *Festo, 122 S. Ct. at 1841* ("The responsibility for changing [settled law] rests with Congress. . . . Fundamental alterations in these rules risk destroying the legitimate expectations of inventors in their property."). Lilly and now this case change the application of the WD test and "up the ante" for disclosure - a situation inventors might have addressed if they could have foreseen that this court would disrupt settled disclosure principles. At this point, however, those inventors have no way to change patents that comply with enablement disclosure, but not the stiffer demands of Lilly.

Replacement of enablement doctrines with an ill-defined general disclosure doctrine of WD imperils the integrity of the patent system. Enablement, arguably the most important patent doctrine after obviousness, has many important applications. Beyond mere adequacy of disclosure, it serves as the line of demarcation between the visionary theorist (adds nothing to the useful arts) and the visionary pioneer (contributes to the useful arts), [**73] see, e.g., *Gould v. Hellwarth, 472 F.2d 1383, 176 USPQ 515 (CCPA 1973)*, and also serves to limit claim

scope thus demarking the boundary between pioneer inventions and patentable improvements, see, e.g., *In re Wright, 999 F.2d 1557 (Fed. Cir. 1993)*. The WD possession test cannot perform these functions. Professor Janis explains that WD provides a blunt tool to measure the sufficiency of disclosure:

> Today, however the written description requirement enjoys a prominence wholly out of proportion to its humble origins.
>
> . . . .
>
> [*983] Recent efforts to elaborate the 'possession' standard both confirm the substantial redundancy of the enablement and written description requirements . . . .
>
> . . . .
>
> The written description requirement is a threat to the coherence of disclosure doctrines . . . .

Janis, Mark D., "On Courts Herding Cats: Contending with the 'Written Description' Requirement (and Other Unruly Patent Disclosure Doctrines)" *2 Wash. U. J. L. & Pol'y 55, 60, 70, 83 (2000)*.

Professors Rai, Mueller, and Wegner, among others, agree with Professor Janis's assessment. Rai, Mueller, supra; Wegner, Harold C. [**74] , "An Enzo White Paper: A New Judicial Standard for a Biotechnology 'Written Description' Under *35 U.S.C. § 112*, P 1" 1 J. Marshall Rev. Intell. Prop. L. 254, 263 (2002) (recognizing "there may very well be problems with the scope of enablement in the facts of the Enzo case," but written description would not apply to "original claims.").

For biotech inventions, according to the Lilly standard, *§ 112*, P 1 requires a precise listing of the DNA sequence nucleotide-by-nucleotide. Enablement, on the other hand, requires that the specification show one of skill in the art how to acquire that sequence on their own. As a test for biotech claims without priority issues, WD may well jeopardize a sizeable percentage of claims filed before the Lilly departure in 1997. These patents had no notice of a change in the statutory standard for disclosure. Moreover the Lilly/Enzo rule prejudices university or small inventors who do not have the expensive and time-consuming resources to process every new biotechnological invention to extract its nucleotide sequence. See, Mueller, supra at 617 ("Lilly . . . will likely chill development."); Sampson, [**75] Margaret, "The Evolution of the Enablement and Written Description Requirements Under *35 U.S.C. § 112* in the Area of Biotechnology." *15 Berkeley Tech. L.J. 1233, 1262 (Fall 2000)* ("The primary argument against the Federal Circuit's heightened written description requirement for biotechnological invention is that . . . it also 'reduces incentives to invest in innovation by depriving potential patentees of the opportunity to fully benefit from their research.'").

Saving the obvious for last, Lilly and this case really cannot depart from decades of established case law on *§ 112*, P 1. Even the court's decision to issue this improved version of Enzo without correcting all the problems does not indicate any acceptance of written description as a general disclosure doctrine for all claims regardless of priority issues. Lilly and this case are panel cases and cannot override the statute that makes enablement the general disclosure doctrine and the vast body of prior case law limiting WD to its original purpose. Sadly, however, this case will perpetuate the confusion.

Conclusion

Written description - a part of the *Patent Act* [**76] since 1870 - has taken on a life separate from its statutory context only since 1967. As long as WD applied only for the reasons that occasioned its judicial creation, it did not disrupt the rest of the *Patent Act*. Two recent cases, however, this case and the 1997 Lilly case, have purported to create a new disclosure doctrine that supplants enablement. Although this court declines to take this occasion to correct those dalliances, the origin and purpose of both *§ 112*, P 1 doctrines serve notice that neither Lilly nor this case properly applies the otherwise orderly disclosure doctrines.

[*984] **APPENDIX**

CCPA

1. *In re Ruschig, 54 C.C.P.A. 1551, 379 F.2d 990 (CCPA 1967)*. "These claims were under rejection by reason of one-year statutory bars which could be overcome only by reliance on the filing date of the present *parent* application which gave rise to the question whether the application contained support for the claims." *Id. at 991.*

I. *In re Ahlbrecht, 58 C.C.P.A. 848, 435 F.2d 908 (CCPA 1971)*. "The parties disagree as to whether the disclosure in the *earlier* application is sufficient under the first paragraph of *35 U.S.C. § 112* [**77] to support the invention claimed in claim 7." *Id. at 909.*

3. *Fields v. Conover, 58 C.C.P.A. 1366, 443 F.2d 1386 (CCPA 1971)*. "Even when considered . . . it falls far short . . . of the 'full, clear, concise, and exact' written description which we have said is necessary to support *subsequently* added claims." *Id. at 1392.*

4. *In re Smith, 59 C.C.P.A. 1025, 458 F.2d 1389 (CCPA 1972)*. "Appellant has no basis on which the

disclosure in the 1947 application may be treated as a description of the subject matter *now* claimed." *Id. at 1394.*

5. *In re Gardner, 475 F.2d 1389 (CCPA 1973).* "Claim 2, which apparently was an original claim, in itself constituted a description in the original disclosure equivalent in scope and identical in language to the total subject matter now being claimed." *Id. at 1391.*

6. *In re Smith, 481 F.2d 910 (CCPA 1973).* "Satisfaction of the description requirement insures that subject matter presented in the form of a claim *subsequent* to the filing date of the application was sufficiently disclosed at the time of filing so that prima [**78] facie date of invention can fairly be held to be the filing date of the application. . . . The specification as originally filed must convey clearly to those skilled in the art the information that the applicant has invented the specific subject matter *later* claimed." *Id. at 914.*

7. *In re Mott, 539 F.2d 1291 (CCPA 1976).* "The issue under this heading is whether appellant's specification, construed in light of the knowledge of those skilled in this art, contains a written description of the subject matter of claims 42, 44, and 46." (Claims 42, 44 and 46 were claims copied from the Taylor patent and put in the application by *amendment.*) *Id. at 1296.*

8. *In re Wertheim, 541 F.2d 257 (CCPA 1976).* "The dispositive issue under this heading is whether appellants' parent and Swiss applications comply with *35 U.S.C. § 112*, first paragraph, including the description requirement, as to the subject matter of these claims. If they do, these claims are entitled to the filing dates of the *parent* application . . . . [A] right of foreign *priority* in appellants' Swiss application will antedate [**79] Pfluger 1966 and remove it as prior art against the claims." *Id. at 261.* "The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter *later* claimed by him." *Id. at 262.*

9. *In re Blaser, 556 F.2d 534 (CCPA 1977).* "The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter *later* claimed by him." *Id. at 537* (quoting *In re Wertheim, 541 F.2d at 262*).

10. *In re Barker, 559 F.2d 588 (CCPA 1977).* "We can find no indication in the specification or claims as originally filed that appellants invented the subject matter *now* claimed." *Id. at 593.*

[*985] 11. *In re Driscoll, 562 F.2d 1245 (CCPA 1977).* "Appellant does not dispute that the appealed claim is anticipated by the Belgian patent if the present application is not entitled to the *earlier* filing date of S.N. 782,756. Consequently, the sole issue with respect to this aspect [**80] of the appeal is whether the disclosure of S.N. 782,756 described the subject matter of claim 13. In resolving this issue, we must view the disclosure of the *earlier* filed application as would a person skilled in the art and determine whether it reasonably conveys the information that as of the filing date thereof appellant had possession of the class of 5-alkylsulfonyl-1, 3, 4-thiadiazole ureas defined in claim 13." *Id. at 1248-49.*

12. *In re Edwards, 568 F.2d 1349 (CCPA 1978).* "The dispositive issue is whether appellants' *parent* application, serial No. 682,560, filed November 13, 1967, complies with the written description requirement of *35 U.S.C. § 112*, first paragraph, vis-a-vis the subject matter of the appealed claim; if it does, then the claim is entitled to the filing date of the *parent* application under *35 U.S.C. § 120*." *Id. at 1351.*

13. *In re Herschler, 591 F.2d 693 (CCPA 1979).* "Appellant concedes that the substance of this rejection is proper if the court finds either the *great-grandparent* application lacks a written description of the *instant* [**81] invention." *Id. at 699.*

14. *In re Rasmussen, 650 F.2d 1212 (CCPA 1981).* "The proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure, therefore, is *§ 112*, first paragraph, not *§ 132*. The latter section prohibits addition of new matter to the original disclosure. It is properly employed as a basis for objection to amendments to the abstract, specifications, or drawings attempting to add new disclosure to that originally presented." *Id. at 1214-15.*

Federal Circuit

1. *In re Kaslow, 707 F.2d 1366 (Fed. Cir. 1983).* "The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the *later* claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language." *Id. at 1375.*

2. *Ralston Purina Co. v. Far-Mar-Co., 772 F.2d 1570 (Fed. Cir. 1985).* "The test for sufficiency of support in a *parent* application [**82] is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the *later* claimed subject matter.'" *Id. at 1575.*

3. *Kennecott Corp. v. Kyocera Int'l., Inc., 835 F.2d 1419 (Fed. Cir. 1987).* "The incorporation of the requirements of *section 112* into *section 120* ensures that the inventor had possession of the *later*-claimed

invention on the filing date of the *earlier* application." *Id. at 1421.*

4. *Utter v. Hiraga, 845 F.2d 993 (Fed. Cir. 1988).* "Hiraga's Japanese specification complies with the written description requirement of *Section 112* if 'the disclosure of the application as originally filed reasonably conveys to the artisan that [Hiriga] had possession at that time of the *later* claimed ['068 interference count] subject matter.'" *Id. at 999.*

5. *Bigham v. Godtfredsen, 857 F.2d 1415 (Fed. Cir. 1988).* "This requirement applies to *priority* claims under *35 U.S.C. § 119.* . . . The test is whether the disclosure of 'halogen,' exemplified by chloro, meets the requirements [**83] of *§ 112* as a written [*986] description of the bromo and iodo species in the context of the specific invention at issue." *Id. at 1417.*

6. *United States Steel Corp. v. Phillips Petroleum Co., 865 F.2d 1247 (Fed. Cir. 1989).* "In the context of *section 120*, in this case, focusing on the filing date requires that the claim of the 851 patent be treated as though it were filed in 1953. Only if that claim would at that time have been correctly rejected for lack of support in the 1953 specification may the patentee be denied use of *section 120* to *predate* the intervening reference to the '300 patent." *Id. at 1251.*

7. *In re Wright, 866 F.2d 422 (Fed. Cir. 1989).* "When the scope of a claim has been changed by amendment in such a way as to justify an assertion that it is directed to a different invention than was the original claim, it is proper to inquire whether the *newly* claimed subject matter was described in the patent application when filed as the invention of the applicant. That is the essence of the so-called 'description requirement' of *§ 112*, first paragraph." *Id. at 424.*

8. *Chester v. Miller, 906 F.2d 1574 (Fed. Cir. 1990).* [**84] "The EIC simply found that the '280 reference (*parent*) did not support the '122 application claims because as to them it failed to meet the written description requirement." *Id. at 1577.*

9. *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555 (Fed. Cir. 1991).* "The purpose and applicability of the 'written description' requirement . . . insure[] that subject matter presented in the form of a claim *subsequent* to the filing date of the application was sufficiently disclosed at the time of filing so that the prima facie date of invention can fairly be held to be the filing date of the application." *Id. at 1562.*

10. *In re Hayes Microcomputer Products, Inc., 982 F.2d 1527 (Fed. Cir. 1992).* "The test for sufficiency of support in a *parent* application is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the *later* claimed subject matter.'" *Id. at 1532.*

11. *Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993).* "Revel bears the burden of proving entitlement to the benefit of his *earlier*-filed Israeli [**85] application date. . . . Revel must prove that his application meets the requirements of *35 U.S.C. § 112*, first paragraph." *Id. at 1169.*

12. *Mendenhall v. Cedarapids, 5 F.3d 1557 (Fed. Cir. 1993).* "Mr. Mendenhall himself testified that he did not have any invention directed to introducing virgin aggregate and RAP as specified in the '904 claims until December 1977, and there is no description of that invention in the parent or grandparent applications. . . . A patentee cannot obtain the benefit of the filing date of an *earlier* application where the claims in issue could not have been made in the *earlier* application." *Id. at 1565-66.*

13. *Eiselstein v. Frank, 52 F.3d 1035 (Fed. Cir. 1995).* "In order to determine whether a prior application meets the 'written description' requirement with respect to *later*-filed claims, the prior application . . . . The test is whether the disclosure of the application relied upon reasonably conveys to a person skilled in the art that the inventor had possession of the claimed subject matter at the time of the *earlier* filing date." *Id. at 1038-39.* [**86]

14. *In re Alton, 76 F.3d 1168 (Fed. Cir. 1996).* "The adequate written description requirement . . . serves 'to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter *later* claimed by him'." *Id. at 1172.*

[*987] 15. *Kolmes v. World Fibers Corp., 107 F.3d 1534 (Fed. Cir. 1997).* "The question raised here is whether the claims *added* by the preliminary amendment to the 1992 *continuation* application find adequate support in the 1990 application sufficient to meet the description requirement of *section 112*, P 1." *Id. at 1539.*

16. *Lockwood v. American Airlines, Inc., 107 F.3d 1565 (Fed. Cir. 1997).* "[A] *prior* application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." *Id. at 1572.*

After LILLY

1. *Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473 (Fed. Cir. 1998).* "Accordingly, his original disclosure serves to limit the permissible breadth [**87] of his *later*-drafted claims." *Id. at 1479.*

2. *Tronzo v. Biomet, Inc., 156 F.3d 1154 (Fed. Cir. 1998).* "For a claim in a *later*-filed application to be entitled to the filing date of an *earlier* application under

35 U.S.C. sec. 120, the *earlier* application must comply with the written description requirement of *35 U.S.C. section 112*, P 1." *Id. at 1158.*

3. *Union Oil Co, of Cal. v. Atlantic Richfield Co., 208 F.3d 989 (Fed. Cir. 2000).* "However, neither the *Patent Act* nor the case law of this court requires such detailed disclosure. . . . *Rather the Patent Act and* this court's case law require only sufficient description to show one of skill in the refining art that the inventor possessed the claimed invention at the time of filing." *Id. at 997.*

4. *Reiffin v. Microsoft Corp., 214 F.3d 1342 (Fed. Cir. 2000).* "In accordance with *§ 120*, claims to subject matter in a *later*-filed application not supported by an ancestor application in terms of *§ 112* P 1 are not invalidated; they simply do not receive the benefit [**88] of the *earlier* application's filing date." *Id. at 1346.*

5. *Lampi Corp. v. American Power Products, Inc., 228 F.3d 1365 (Fed. Cir. 2000).* "For a claim in a *later*-filed application to be entitled to the filing date of an *earlier* application under *35 U.S.C. 120*, the *earlier* application must comply with the requirement of *35 U.S.C. § 112*, P 1." *Id. at 1377.* "The requirement is met if 'the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the *later* claimed subject matter.'" *Id. at 1378.*

6. *Purdue Pharma L.P. v. Faulding, Inc., 230 F.3d 1320 (Fed. Cir. 2000).* "We conclude that the district court did not commit clear error in finding that nothing in the '688 application 'necessarily' . . . described the *later* claimed subject matter of the '360 patent." *Id. at 1327.*

7. *TurboCare Div. Of Demag Delaval Turbomachinery Corp. v. General Elec. Co., 264 F.3d 1111 (Fed. Cir. 2001).* "The written description requirement and its corollary, the new matter [**89] prohibition of *35 U.S.C. § 132*, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date. When the applicant adds a claim or otherwise amends his specification after the original filing date, as Brandon did in this case, the new claims or other added material must find support in the original specification." *Id. at 1118.*

LINN, Circuit Judge, with whom RADER and GAJARSA, Circuit Judges, join, dissenting from the court's decision not to the hear the case en banc.

I am in agreement with much of the panel's reasoning in the revised opinion, [*988] but part company with the panel's treatment of written description and enablement issues, most notably in the text dealing with the in ipsis verbis issue.

With all due respect, the panel opinion in my view conflates and perpetuates the confusion our precedent has engendered between written description as a separate requirement ("possession of the invention")--an issue relevant to priority--and enablement-- an issue relevant to the sufficiency of the disclosure. The notion of having to show "possession of the invention" [**90] was discussed in *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991)* and other cases from our court as a convenient way to measure or test entitlement of later filed claims to an earlier priority date. It was not and should not be a test for sufficiency of disclosure, per se. It should have no place in and does not aid in the disposition of cases where the claims in question are part of the original disclosure. In those cases, entitlement to the filing date is inherent in that the claims themselves--having been filed as part of the original application--provide their own written description.

35 U.S.C. § 112 requires a written description of the invention, but the measure of the sufficiency of that written description in meeting the conditions of patentability in paragraph 1 of that statute, either by reference to a microorganism deposit or in terms in ipsis verbis with the language of the claims, should depend solely on whether it enables any person skilled in the art to which the invention pertains to make and use the claimed invention. Where priority is not an issue, as in the present case, the focus once a written [**91] description has been found should be on whether the description meets the enablement requirement. Satisfaction of the "possession of the invention" test simply is not relevant.

The question presented by *35 U.S.C. § 112*, paragraph 1, is not, "Does the written description disclose what the invention is, or does it merely describe what it does?" The question is, "Does the written description describe the invention recited and described in the claims--themselves part of the specification--in terms that are sufficient to enable one of skill in the art to make and use the claimed invention?" That is the mandate of the statute and is all our precedent, prior to *Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997)* and the present case, demand. For original claims, where priority is not an issue, the notion of possession of the invention is not germane, the claim itself evidencing possession of the invention as of the filing date. In the panel opinion, the discussion of the in ipsis verbis issue properly addresses enablement issues but does so in words not of enablement but of "possession of the [**92] invention." This conflates the two unrelated issues,

elevates "possession" to the posture of a statutory test of patentability--which it is not--and fosters further confusion in what is already a confusing area of our precedent.

The U.S. Patent and Trademark Office ("PTO") aptly states the reason why this case should be taken en banc: "although this Court has addressed the 'written description' requirement of *section 112* on a number of occasions, its decisions have not taken a clear and uniform position regarding the purpose and meaning of the requirement." PTO amicus brief at 4.

This is an area of law that is of significant importance to the biotech industry and affects how patent applications are drafted, prosecuted and will be enforced in this and other areas of emerging technology. When patent attorneys set out to write patent applications, they do so for an educated audience--those skilled in the [*989] art--and attempt to describe the invention in a way that enables those of ordinary skill to make and use the invention as claimed. Before the decision in Lilly, the practicing bar had accepted and found workable the notion elucidated in our precedent that *§ 112* requires a written [**93] description sufficient to enable one of ordinary skill in the art to make and use the claimed invention--i.e., enablement. Lilly changed the landscape and engendered the debate the panel opinion in this case perpetuates.

Some have praised Lilly for maintaining the integrity of patent disclosures and for curbing patent filings for inventions that have not yet been made but are just nascent ideas. Others have been sharply critical of Lilly. The debate is well framed by the panel opinion and the contemporaneous dissent of Judge Rader. Those opinions highlight the uncertainty this issue raises in how inventions are protected, in how the PTO discharges its responsibilities, and in how business is conducted in emerging fields of law. These uncertainties will be left unresolved until we clarify this en banc. The issue is important, is ripe for us to consider, and deserves to be clarified, one way or the other. For these reasons, I respectfully dissent from the court's declining to consider this case en banc.

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